RECEIVED AT DRUG SAFETY SURVEILLANCE
19-JUN-1998-0469

Mc

cNEIL CONSUME
FORT WASHI

Individual Safety Report
3096929-X-00

Page ____ of ____

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	adult	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
(X) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
( ) other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
07/18/96	06/10/98

5. Describe event or problem

Notification via attorney letter of LIVER DAMAGE ("hepatic toxicity") allegedly associated with the use of an unknown TYLENOL® acetaminophen product in client. Attorney reports, on or about 7/18/96, patient prescribed to TYLENOL. As a result of such prescription, patient was admitted to the Intensive Care Unit. She reportedly underwent medicinal treatment for "hepatic toxicity" among various other associated conditions for several days. Reportedly patient's condition was caused due to her prescribing of the TYLENOL product. No further information was provided.

6. Relevant tests/laboratory data, including dates

unknown

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TYLENOL Analgesic Unknown
#2

JUN 1 9 1998

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown dose, po	#1 start date 7/18/96
#2	#2

4. Diagnosis for use (indication)

#1 unknown
#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)	7. Exp. date (if known)
#1 unknown	#1 unknown
#2	#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
( ) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
(X) other: attorney

4. Date received by manufacturer (mo/day/yr): 06/08/98

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
(X) initial ( ) follow-up #

8. Adverse event term(s)

LIVER DAMAGE

9. Mfr. report number

0989282A

E. Initial reporter

1. Name, address & phone #

[redacted], Attorney At Law
[redacted]

JUN 22 1998

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes (X) No	attorney	( ) Yes ( ) No (X) Unk

FDA
Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.